

8-18-0

Attorney Docket No. 023542-0145

### HE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Moser et al.

Title:

**POLYMERASE INHIBITOR AND** METHOD OF USING

**SAME** 

Application No.:

10/551,705

International

04/01/2004

Filing Date:

371(c) Date:

Not yet assigned

Examiner:

Not yet assigned

Art Unit:

Not yet assigned

Confirmation No.: Not yet assigned

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#### **TRANSMITTAL**

Transmitted herewith please find the following documents for the above-identified patent application.

- Information Disclosure Statement Under 37 C.F.R. § 1.56 (2 pages). [X]
- [X] Form PTO/SB/08 (4 pages) listing 82 references, enclosing copies of 11 foreign patent documents and copies of 23 non-patent documents (34 total copies).

Although the Applicants believe that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-2350.

Respectfully submitted,

Date 08-17-06

**FOLEY & LARDNER LLP** Customer Number: 61495

Stephanie H. Vavra

Attorney for the Applicants

Registration No. 45,178

Telephone: (414) 319-7305

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# INFORMATION DISCLOSURE STATEMENT **UNDER 37 C.F.R. § 1.56**

Submitted herewith on Form PTO/SB/08 is a listing of documents known to the Applicants in order to comply with the Applicants' duty of disclosure pursuant to 37 C.F.R. § 1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 C.F.R. § 1.97 and § 1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 C.F.R. § 1.56(b). The Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 C.F.R. § 1.97(b), before the mailing date of the first Office Action on the merits.

### RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

The Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with M.P.E.P. § 609.

Although the Applicants believe that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-2350.

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AUG 17 2006

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Under the Paperwork Reduced number.

Substitute for form 1449B/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 10/551,705 STATEMENT BY APPLICANT 04/01/2004 (371(c) Date not yet assigned) International Filing Date Michael James Moser **First Named Inventor** Date Submitted: August 17, 2006 **Group Art Unit** Not yet assigned **Examiner Name** (use as many sheets as necessary) Not yet assigned of Attorney Docket Number 023542-0145 Sheet 1

		<u> </u>		U.S. PATENT DOCUMENTS		
Examiner Initials*	Cite No.1	U.S. Patent D	Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/AB/	A1.	2006/0078936	A1	Grenier et al.	04-13-2006	
8	A2.	2005/0084894	A1	Brow et al.	04-21-2005	
	A3.	2005/0014163	A1	Dong et al.	01-20-2005	•
	A4.	2004/0106108	A1 .	Grenier et al.	06-03-2004	
	A5.	2003/0194705	A1	Schroth	10-16-2003	
	A6.	2002/0150900	A1	Marshall et al.	10-17-2002	
	A7.	2002/0132221	A1	Chee et al.	09-19-2002	
	A8.	2002/0055104	A1	Michelotti	05-09-2002	
	A9.	6,977,161	B2	Grenier et al.	12-20-2005	
	A10.	6,833,257	B2	Lee et al.	12-21-2004	
8	A11.	6,627,456	B1	Benner	09-30-2003	
8	A12.	6,617,106	B1	Benner	09-09-2003	
000	A13.	6,548,250	B1	Sorge	04-15-2003	
	A14.		B1	Benner	09-03-2002	
2000	A15.	6,294,336	B1	Boyce-Jacino et al.	09-25-2001	
200	A16.		B1	Nolan et al.	09-11-2001	
		6,232,462	B1	Collins et al.	05-15-2001	
	A18.		B1	Kurn et al.	03-13-2001	
	A19.	6,140,496		Benner	10-31-2000	
	A20.	6,057,107		Fulton	05-02-2000	
	A21.	6,054,270		Southern	04-25-2000	
	A22.	6,046,807		Chandler	04-04-2000	
-	A23.			Benner	03-14-2000	
	A24.			Wang et al.	12-28-1999	
000	A25.	6,001,983		Benner	12-14-1999	
	A26.	5,965,364		Benner	10-12-1999	,
	A27.	5,958,784		Benner	09-28-1999	
0		5,928,869		Nadeau et al.	07-27-1999	
	A29.	5,856,092		Dale et al.	01-05-1999	
000	A30.	5,846,717		Brow et al.	12-08-1998	
8	A31.	5,843,669		Kâiser et al.	12-01-1998	
	A32.	5,736,330		Fulton	04-07-1998	
0000	A33.	5,705,621		Ravikumar	01-06-1998	
8000	A34.	5,681,702		Collins et al.	10-28-1997	
	A35.	5,679,524		Nikiforov et al.	10-21-1997	
	A36.	5,605,794		Rust et al.	02-25-1997	,
	A37.	5,604,097		Brenner	02-18-1997	
000	A38.	5,470,974		Summerton et al.	11-28-1995	
	A39.	5,432,272		Benner	07-11-1995	
$\nabla I Z$	A40.	5,412,088		Jones et al.	05-02-1995	
₩.	A41.	5,210,015		Gelfand et al.	05-11-1993	

Examiner Signature	/Amy Bowman/	Date Considered	06/17/2010

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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	Substitute for form	1449B/	PTO	Complete if Known			
	INFORMATION DI	SCLO	SURE	Application Number	10/551,705		
STATEMENT BY APPLICANT  Date Submitted: August 17, 2006				International Filing Date	04/01/2004 (371(c) Date not yet assigned)		
				First Named Inventor	Michael James Moser		
				Group Art Unit	Not yet assigned		
	(use as many sheets	as ne	cessary)	Examiner Name	Not yet assigned		
Sheet	2	of	4	Attorney Docket Number	023542-0145		

	U.S. PATENT DOCU	MENTS	
U.S. Patent Docum	nent		
A42. 5,177,064	Bodor	01-05-1993	
A43. 5,126,439	Rappaport	06-30-1992	
A44. 4,996,143	Heller et al.	02-26-1991	
A45. 4,800,159	Mullis et al.	01-24-1989	
A46. 4,683,202	Mullis	07-28-1987	
A47. 4,683,195	Mullis et al.	07-28-1987	
A48. 4,458,066	Caruthers et al.	07-03-1984	

		<u> </u>	UNPUBLISI	HED U.S. PATENT APPLICATION	DOCUMENTS	
Examiner Initials*	Cito	U.S. Patent Ap		Name of Patentee or Applicant of Cited Document	Filing Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	Cite No. <sup>1</sup>	Serial Number	Kind Code <sup>2</sup> (if known)			

	-			FC	REIGN PATENT DOCUMEN	TS		
Examiner Initials*	Cite No. <sup>1</sup>	F Office	oreign Patent D	Ocument Kind Code <sup>5</sup> (if known)	Name of Patentee or	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	A49.	WO	01/90417	A2	Marshall et al.	11-29-2001		
	A50.	EP	0 915 174	A1	Karube et al.	05-12-1999		
	A51.	wo	98/14610	A2	O'Neill et al.	04-09-1998		
	A52.	WO	97/46711	A1	Guo et al.	12-11-1997		
	A53.	EP	0 742 287	A2	McGall et al.	11-13-1996		
	A54.	WO	96/31622	A1	Southern et al.	10-10-1996		
	A55.	wo	94/21820	A1	Wallace	09-29-1994		
	A56.	wo	92/11389	A1	Erlich et al.	07-09-1992		
	A57.	EP	0 416 817	B1	Newton	03-13-1991	•	
	A58.	EP	0 382 433	B1	Garman et al.	08-16-1990		
	A59.	WO	90/06042	A2	Hornes et al.	06-14-1990		
								1

Examiner Signature	Date Considered	

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	(use as many s	heets as ne	cessary)	Examiner Name	Not yet assigned		
Sheet	3	of	4	Attorney Docket Number	023542-0145		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A60.	BIGGINS et al., "A continuous assay for DNA cleavage: The application of "break lights" to enediynes, iron-dependent agents, and nucleases", PNAS, Vol. 97, No. 25, December 5, 2000 (pp. 13537-13542).	
	A61.	COBIANCHI et al., "Enzymes for Modifying and Labeling DNA and RNA", Methods in Enzymology, Vol. 152 Copyright © 1987 by Academic Press, Inc., (pp. 94-110).	
	A62.	HALL et al., "Sensitive detection of DNA polymorphisms by the serial invasive signal amplification reaction", PNAS, Vol. 97, No. 15, July 18, 2000 (pp. 8272-8277).	
	A63.	HORLACHER et al., "Recognition by viral and cellular DNA polymerases of nucleosides bearing bases with nonstandard hydrogen bonding patterns", <i>Proc. Natl. Acad. Sci.</i> , Vol. 92, July 1995 (pp. 6329-6333).	
	A64.	JOHNSON et al., "A third base pair for the polymerase chain reaction: inserting isoC and isoG", Nucleic Acids Research, Vol. 32, No. 6, 2004, (pp. 1937-1941).	
<u></u>	A65.	JURCZYK et al., "Synthesis of 2'-Deoxyisoguanosine 5'-Triphosphate and 2'-Deoxy-5-methylisocytidine 5'- Triphosphate", Helyetica Chimica Acta, Vol. 82, 1999 (pp. 1005-1015).	
	A66.	LUTZ, MICHAEL J. et al., "Differential discrimination of DNA polymerases for variants of the non-standard nucleobase pair between xanthosine and 2,4-diaminopyrimidine, two components of an expanded genetic alphabet". Nucleic Acids Research, Vol. 24, No. 7, 1996 (pp. 1308-1313).	
	A67.	LUTZ, STEFAN et al., "An <i>in vitro</i> screening technique for DNA polymerases that can incorporate modified nucleotides. Pseudothymidine as a substrate for thermostable polymerases", <u>Nucleic Acids Research</u> , Vol. 27, No. 13, 1999 (pp. 2792-2798)	
	A68.	MOSER et al., "Quantifying Mixed Populations of Drug-Resistant Human Immunodeficiency Virus type 1",	
	A69.	MOSER et al., "Enzymatic repair of an expanded genetic information system", Nucleic Acids Research, Vol. 31, No. 27, 2003 (pp. 5048-5053).	
	A70.	NEWTON et al., "The production of PCR products with 5' single-stranded tails using primers that incorporate novel phosphoramidite intermediates", <u>Nucleic Acids Research</u> , Vol. 21, No. 5, 1993 (pp. 1155-1162)	
	A71.	PICCIRILLI et al., "Enzymatic incorporation of a new base pair into DNA and RNA extends the genetic	
	A72.	RANDERATH et al., " <sup>3</sup> H and <sup>32</sup> P Derivative Methods for Base Composition and Sequence Analysis of RNA" Methods in Enzymplogy, Vol. 65, Copyright © 1980 by Academic Press, Inc., (pp. 638-681).	
	A73.	SEPIOL et al., "Tautomerism of Isoguanosine and Solvent-Induced Keto-Enol Equilibrium", Z. Naturforsch, 1976 (pp. 361-370).	
	A74.	SISMOUR et al., "The use of thymidine analogs to improve the replication of an extra DNA base pair: a synthetic biological system". Nucleic Acids Research, Vol.33, No. 17, 2005 (pp. 5640-5646).	
	A75.	SISMOUR et al., "PCR amplification of DNA containing non-standard base pairs by variants of reverse transcriptase from Human Immunodeficiency Virus-1", <u>Nucleic Acids Research</u> , Vol. 32, No. 2, 2004 (pp. 728-735).	
	A76.	SWITZER et al., "Enzymatic Recognition of the Base Pair between Isocytidine and Isoguanosine", Biochemistry, Vol. 32, No. 39, 1993 (pp. 10489-10496).	
	A77.		

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Sheet	4		of	4	Attorney Docket Number	023542-0145			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
/AB/	A78.	into RNA", J. Am. Chem. Soc., Vol. 115, No. 11, 1993 (pp. 4461-4467).	
/AB/	A79.	VON KROSIGK et al., "pH-Independent Triple Helix Formation by an Oligonucleotide Containing a Pyrazine Donor-Donor-Acceptor Base", J. Am. Chem. Soc., Vol. 117, No. 19, 1995 (pp. 5361-5362).	
/AB/	A80.	WALKER et al., "Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system", Proc. Natl. Acad. Sci., Vol. 89, January 1992 (pp. 392-396).	
	A81	WATANABE et al "Two-Step Synthesis of 2,5'-Anhydronucleosides From Thymidine, 2'-Deoxyuridine,	00000000
/AB/	A82.	and 2'-Deoxy-5-fluorouridine", <u>Nucleic Acid Chemistry</u> (pp. 273-277).  ZUBAY, "A Case for an Additional RNA Base Pair in Early Evolution", Reprint from: <u>The Roots of Modern</u> Biochemistry, © 1988 Walter de Gruyter & Co., Berlin, New York (4 pp.).	

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Examiner Signature	/Amy Bowman/	Date Considered	06/17/2010

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